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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/468,147	12/21/99	SCHLAUDER G	6232.US.P1

EXAMINER	
BRUMBACK, B	
ART UNIT	**PAPER NUMBER**
1642	10

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023492
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HM12/0725

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/468,147	Schlauder et al.
Examiner	**Art Unit**
Brenda Brumback	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 19, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above, claim(s) *7-11, 16-23, and 27-43* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6, 12-15, and 24-26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, Species SEQ ID NO:91, in Paper No. 9 is acknowledged. Applicant's arguments regarding the restriction requirement as it applies to Groups I and II were persuasive. Therefore Group II has been rejoined with Group I.

2. Pending claims are 1-43. Claims 21-23 and 27-43 are withdrawn from consideration as directed to nonelected inventions. Claims 7-11 and 16-20 are withdrawn from consideration as directed to nonelected species. Claims 1-6, 12-15, and 24-26 are under examination to the extent that they read on SEQ ID NO:91.

Information Disclosure Statement

3. The Information Disclosure Statement filed 04/12/2000 has been considered. A signed copy is attached hereto. Please NOTE: Reference C16 (MEDLINE Abstract) was not considered, as no copy was provided with the IDS and the abstract was not found in parent application No. 09/173,141. Furthermore, no author or date of publication was provided for the abstract. Each publication referenced in an IDS must be identified by author (if any), title, relevant pages of the publication, date and place of publication (see MPEP 609 A(1)).

Priority

4. A review of the priority documents shows support for the US-type or US-subtype of hepatitis E virus (HEV) in the disclosure of Provisional Application 60/061,199 filed 10/15/1997. Support for SEQ ID NO:91 was not found in the provisional application, but was found in parent application 09/173,141. Therefore, for purposes of examination, the priority date for claims 1-5, 13-14, and 24-26 drawn to a US-type or US-subtype of HEV has been determined to be 10/15/1997 and the priority date for claims 6, 12, and 15 drawn specifically to SEQ ID NO:91, has been determined to be 10/15/1998.

Claim Rejections - 35 USC § 112

5. Claims 1-6, 12-15, and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite a US-type hepatitis E virus (HEV) or a naturally occurring variant thereof. While the specification discloses naturally occurring variants of the polypeptides defined by SEQ ID NO: 91, 92, and 93 in terms of percent identity (see page 21, line 20, through page 22, line 2), the specification fails to teach the metes and bounds of a naturally occurring variant of the HEV virus itself. Absent such disclosure, the metes and bounds of the claimed invention cannot be ascertained and the claims are indefinite.

Claim 26 appears to be of improper dependency, as claim 41 from which claim 26 depends, does not recite a mammalian cell line. For purposes of examination, claim 26 has been interpreted as depending from claim 25. Correction is required.

6. Claims 1-6 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to a method of detecting the presence of a US-type HEV or a naturally occurring variant thereof in a test sample comprising contacting the sample with a binding partner that binds specifically to a marker for the virus, wherein the marker is an antibody.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that specific antibodies are produced in response to infection with or exposure to a virus. The art teaches that while detection of specific antibodies directed against a particular virus in a sample is indicative of present or past infection with that virus, specific antibody is not in and of itself a marker for the presence of the virus itself in that sample (see Ray et al., pages 1218-1226, in Clinical Diagnosis & Management by Laboratory Methods, Henry, J.B. ed., W.B. Saunders Company, Philadelphia, especially pages 1225-1226, *Serodiagnosis*). Furthermore, the art teaches that variant strains of a virus may or may not elicit production of antibodies of the same immunoreactivity.

The amount of direction or guidance present and the presence or absence of working examples: The disclosure teaches detection of antibodies to HEV and teaches that the presence of antibodies in the serum is indicative of HEV infection or exposure (see page 84, lines 1-5, and page 102, lines 1-2). The specification does not teach that detection of specific antibody is indicative of the actual presence of the virus in that particular test sample. There are no working examples demonstrating a correlation between antibody detection and viral presence in a

particular test sample. Furthermore, the disclosure fails to teach any naturally occurring variants of US-type HEV and fails to teach whether these variants would be expected to elicit antibodies with the same reactivity as the original virus.

The breadth of the claims and the quantity of experimentation needed: Because the claims are drawn to a method of detecting the presence of US-type HEV or a naturally occurring variant thereof in a test sample comprising detection of an antibody as a marker, and because the art teaches that 1) there is no correlation between antibody detection and viral presence in a test sample and 2) that variants of a virus may or may not elicit antibodies with the same immunoreactivity, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention.

7. Claims 1 and 12-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of the presence of a US-type HEV in a test sample selected from stool, bile and liver cells, does not reasonably provide enablement for detection of the presence of a US-type HEV in other types of samples, such as serum and blood samples, for example. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The nature of the invention: The claimed invention is drawn to a method of detecting the presence of a US-type HEV in a test sample comprising contacting the sample with a binding

partner that binds specifically to a marker for the virus, wherein the marker is a virus specific polypeptide chain (antigen). The specification discloses the test sample of the present invention as encompassing serum, plasma, blood, saliva, sputum, semen, urine, feces, bile, spinal fluid, and tissue samples, among others (see page 15, lines 2-10).

The state of the prior art and the predictability or lack thereof in the art: The art teaches that antibodies to HEV are detectable in serum or plasma samples. The art teaches that virus particles and/or viral antigens are detectable in stool specimens, in bile of infected animals, and in liver tissue (see Krawczynski, K. Hepatology 17(5):932-941, 1993, of record in Paper # 3, especially page 933, last paragraph of the page, and page 834, first paragraph). The art does not teach that anti-viral antibodies are detectable in samples other than serum or plasma and does not teach that viral particles or antigens are detectable in samples such as blood, serum, plasma, sputum, semen, urine, and spinal fluid, for example.

The amount of direction or guidance present and the presence or absence of working examples: The specification discloses and provides working examples for detection of antibodies directed against US-type HEV and detection of US-type HEV RNA in serum samples; it does not disclose detection of antibodies in any other type of sample. The specification does not disclose methods for detection of US-type HEV polypeptides or antigens in any type of test sample. There are no working examples describing detection of US-type HEV polypeptides in any test sample.

The breadth of the claims and the quantity of experimentation needed: Given the teachings in the art that anti-HEV antibodies and HEV particles and/or antigens are detectable only in specific types of samples and absent any disclosure in the present specification as to how to detect anti-HEV antibodies and US-type HEV antigens and/or particles in other types of samples, one of skill in the art would be unable to practice the claimed invention commensurate in scope with the claims.

8. Claims 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of a US-type HEV in a hepatocytic culture system, does not reasonably provide enablement for detection of US-type HEV in other mammalian cell lines or in human fetal kidney cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The nature of the invention: The claimed invention is drawn to a method of detecting the presence of a US-type HEV in a test sample, comprising contacting the sample with a binding partner that binds specifically to a marker for the virus, wherein the test sample is a mammalian cell line or is specifically a human fetal kidney cell line. Thus, the claimed invention encompasses detection of HEV-infected cells in culture and specifically encompasses detection of HEV-infected human fetal kidney cells *in vitro*.

The state of the prior art and the predictability or lack thereof in the art: The prior art teaches that HEV does not efficiently infect or replicate in cell lines *in vitro*. The prior art teaches that the only type of cells which have been found to support the replication of HEV *in vitro* are hepatocytes (see Reyes et al., Seminars in Liver Disease, 12(3):289-300, the paragraph bridging pages 90-291).

The amount of direction or guidance present and the presence or absence of working examples: The specification fails to disclose infection or replication of US-type HEV in human fetal kidney cells, or in any other cell lines in culture. There is a single working example (pages 104-105, Example 12) drawn to detection of HEV RNA in primary human fetal kidney cells. The art teaches that primary human fetal kidney cells are not considered to be a "cell line" per se, because they cannot be subcultured *in vitro* without loss of characteristic morphology and changes in viral susceptibility (see Schmidt, N.J., pp. 79-85 in Diagnostic Procedures for Viral and Rickettsial Infections, 4th ed. , 1969, Lennette et al., ed., American Public Health Association, Inc.). Furthermore, the working example does not disclose HEV infection or replication in human fetal kidney cells and does not disclose detection of HEV in kidney cells. Rather, the specification discloses detection of US-type HEV RNA in a positive serum sample mixed with kidney cells, *i.e.*, negative human kidney cells "spiked" with HEV US-2 positive serum (see page 104, lines 9-13).

The breadth of the claims and the quantity of experimentation needed: As set forth *supra*, the claims are drawn to detecting the presence of a US-type HEV in a mammalian cell line and

specifically in a human fetal kidney cell line. The art teaches that HEV does not infect or replicate in mammalian cell lines other than human hepatocytes. The specification does not disclose a human fetal kidney cell line which supports infection and replication of US-type HEV and does not disclose detection of HEV in human fetal kidney or any other type of cells. Given the teachings of unpredictability in the prior art regarding HEV infection of cells other than hepatocytes and the lack of sufficient disclosure in the specification to overcome those teachings, one of skill in the art would be unable to practice the claimed invention commensurate in scope with the claims absent undue experimentation.

Claim Rejections - 35 USC § 101

9. Claims 1-6, 12-15, and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus comprising US-types or US-subtypes of HEV and naturally occurring variants thereof. A

description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). While applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus.

There are two species disclosed that are within the scope of the claimed genus, *i.e.* two isolates of US-type HEV. There is no disclosure of any of the variant species encompassed within the claimed genus. The disclosure of even a single species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species, *i.e.* naturally occurring variants, that are not described. There is no disclosure of any representative naturally occurring variants and no disclosure of any structural feature that is common to the variant members of the genus. Consequently, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of viruses which comprises US-types and subtypes of HEV and naturally occurring variants thereof. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

a. Claims 1-5 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson et al. (Journal of Virological Methods, 38:175-186, 1992) in view of Schlauder et al. (IX Triennial International Symposium on Viral Hepatitis and Liver Disease, 04/1996; abstract A103).

The claimed invention is drawn to a method of detecting the presence of a US-type or US-subtype HEV in a test sample comprising contacting the sample with a binding partner that binds specifically to a marker for the virus to form a complex and detecting the presence of the complex, wherein the marker is an IgG or IgM antibody and the binding partner is a polypeptide immobilized on a solid support. Although the presence of virus-specific antibody is not indicative of the presence of the virus itself in the sample, as was set forth *supra*, the claimed invention has been interpreted as drawn to a method for detection of virus specific antibody as indicative of exposure to or infection with a US-type HEV.

Dawson et al. teach a method of detecting the presence of IgG and IgM antibodies directed against HEV comprising contacting a serum or plasma sample with an isolated polypeptide specific for HEV (see the Summary and page 177, first paragraph). Dawson et al. teach immobilizing the polypeptide on a solid support and detecting the antibody-polypeptide complex in a standard ELISA format (see page 178, first through fourth paragraphs). Dawson et al. differ from the claimed invention in that they describe HEV isolates from Mexico, Burma, Somalia, and Pakistan (see the abstract), rather that as a US-type or subtype.

Schlauder et al. teach identification of an isolate of HEV from an acute case of hepatitis E infection in the United States that is highly divergent from the Burmese and Mexican isolates. Schaluder et al. teach that the US HEV represents a third and unique group of HEV (see the last sentence of the abstract).

One of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to have applied the method of testing for the presence of HEV specific IgG and IgM antibodies taught by Dawson et al. as a means of detecting infections due to or exposure to the US-type HEV disclosed by Schlauder et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do so for identification of one of the etiologic agents of hepatitis infection in the United States.

b. Claims 6, ~~12, and 15~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson et al. in view of Schlauder et al. 1996 and in light of Schlauder et al. (Journal of General Virology 79:447-456, March 1998; hereinafter Schlauder 1998).

The claimed invention has been interpreted as drawn to a method of detecting the US-type or US-subtype HEV comprising contacting a test sample with a binding partner that binds specifically to a marker to form a complex and detecting the presence of the complex, wherein the marker is an antibody and the binding partner is a polypeptide consisting of SEQ ID NO:91 immobilized on a solid support.

As described *supra*, Dawson et al. teach a method of detecting HEV specific antibody comprising contacting a test sample with a polypeptide specific for HEV immobilized on a solid support so that an antigen/antibody complex is formed and detecting the presence of the complex in a standard ELISA. Schlauder 1996 teaches a US-type or US-subtype HEV. Neither Dawson et al. nor Schlauder 1996 teaches the polypeptide as consisting of SEQ ID NO:91.

Schlauder 1998 teaches a US variant of HEV which encodes the polypeptide of SEQ ID NO:90 (see Protein Sequence Search, database SPTREMBL, 05/30/2001, Result 1). Schlauder teach generation of synthetic polypeptides based on the US HEV sequence and development of ELISA for detection of IgG and IgM antibodies employing the synthetic polypeptides (see Schlauder 1998, the paragraph bridging pages 452-454). Finally, Schlauder 1998 teaches that epitopes of the US-type of HEV are diagnostically useful for identifying and distinguishing infections with US-type of HEV.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have employed the polypeptide antigen taught by Schlauder 1998 in the method disclosed by Dawson in view of Schlauder 1996, because Schlauder 1998 teaches that the polypeptide comprises diagnostically useful epitopes for identifying antibodies against the US-type of HEV.

c. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson et al. in view of Schlauder 1996, as applied to claim 1 above, and further in view of Reyes et al.

The claimed invention has been interpreted as drawn to a method of detecting the US-type or US-subtype HEV comprising contacting a test sample with a binding partner that binds specifically to a marker to form a complex and detecting the presence of the complex, wherein the test sample is a mammalian cell line.

As previously described, Dawson et al. teach a method of detecting anti-HEV antibodies in a test sample comprising reacting the test sample with HEV-specific polypeptides for formation of an antigen/antibody complex and detection of the complex formed via standard ELISA. Schlauder 1996 teaches the U.S. type or US-subtype of HEV. Neither Dawson et al. nor Schlauder 1996 teach application of the ELISA for detection of viral antigens or polypeptides in a cell line.

Reyes et al. teach that HEV infects and replicates in mammalian hepatocytes and hepatocytic cell lines. Reyes et al. teach that development of an efficient *in vitro* culture system

for hepatitis viruses is needed for virus propagation in order to facilitate biochemical analysis and ultimately vaccine formulation (see page 290, column 2, first full paragraph, through the paragraph bridging pages 290-291).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the ELISA test disclosed by Dawson et al. in view of Schlauder 1996 as a culture confirmation test for detection of virus propagation in an hepatocytic cell line. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to facilitate analysis of the virus, for development of diagnostic antigens, and/or for formulating vaccine compositions.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(WO 95/02070)

Abbott teachs a method of detecting the presence of anti-HEV anttibody in a test sample comprising contacting the test sample with one or more synthetic peptides specific for HEV to produce an antibody/peptide complex and detecting the presence of the complex as indicative of the presence of the antibody in the test sample.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB
July 24, 2001

Brenda Brumback
Brenda Brumback,
Patent Examiner

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.